Page 1 of 3

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

ADAPt™ Universal Balloon Open Access Port

OCT - 4 2011

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8049
Fax: 919-433-4996

B. Contact Person

Natalie Smith
Regulatory Affairs Specialist

C. Date Prepared

August 23, 2011

D. Device Name

Trade Name: ADAPt™ Universal Balloon Open Access Port

Common Name: Surgical Trocar

Classification Name: Endoscope and Accessories (21 CFR 876.1500, Product Code GCJ)

E. Device Description

ADAPt™ Universal Balloon Open Access Port is used to establish a port of entry into the abdominal cavity, facilitating the access of various diameter devices, while maintaining insufflation at the surgical site. The port is positioned into the peritoneum during minimally invasive surgical procedures, in order to provide a pathway for the insertion and removal of various sized surgical devices. ADAPt™ Universal Balloon Open Access Port is intended to be used by trained physicians.

F. Indications for Use

The Universal Balloon Open Access Port is indicated for use in thoracic, abdominal, and gynecologic minimally invasive surgical procedures to provide a pathway for the introduction of endoscopic surgical devices.

G. Contraindications

Where minimally invasive techniques are contraindicated, other methods and instrumentation should be employed.

H. Substantial Equivalence

The proposed Universal Balloon Open Access Port is substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
ADAPt™ Balloon Open Access Port Model 41244	Teleflex Medical, Inc. / Taut, Inc.	K023261	12/13/02
ADAPt™ Universal Laparoscopic Port	Teleflex Medical, Inc. / Taut, Inc.	K082156	09/10/2008

I. Comparison To Predicate Devices

The essence of this change is the selection of previously approved key features from K023261; *ADAPt™ Balloon Open Access Port Model 41244* and K082156; *ADAPt™ Universal Laparoscopic Port*, to produce a new consolidated design. No new Indications for Use, patient contacting materials, manufacturing processes, or risks have been introduced with these proposed modifications.

The new consolidated design of the *ADAPt™ Universal Balloon Open Access* features the Balloon from K023261 with the additional features of the Universal and Duckbill Seals arising from K082156. A polypropylene Ring Clamp (non-patient contacting) has replaced an acrylic cannula clamp (aka H clamp) from the previous design and the definition of the cannula working length has been clarified. In doing so, the actual working length of the Access Port has been lengthened to 125mm which is a length previously cleared for port access under K023261. All other proven attributes of the ADAPt™ Balloon Open Access Port remain the same.

J. Materials

All patient contacting materials are in compliance with ISO10993-1.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed *ADAPt™ Universal Balloon Open Access Port* and the predicate has been performed. The results of this comparison demonstrate that the *ADAPt™ Universal Balloon Open*

Access Port is equivalent to the marketed predicate devices in performance characteristics. Page 3 of 3

L. Performance Data

The bench testing has been performed to verify that the performance of the proposed *ADAPt™ Universal Balloon Open Access Port* is substantially equivalent to the predicate device, and that the *ADAPt™ Universal Balloon Open Access Port* will perform as intended.

L. Conclusion

Based upon the comparative test results, the proposed *ADAPt™ Universal Balloon Open Access Port* is substantially equivalent in performance to the predicate devices cleared to market via 510(k) K023261 and K082156. The modifications made to the proposed *ADAPt™ Universal Balloon Open Access Port* do not introduce any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Teleflex Medical, Inc.
% Ms. Natalie Smith
Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, North Carolina 27709

OCT - 4 2011

Re: K112456
Trade/Device Name: Universal Balloon Open Access Port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 13, 2011
Received: September 23, 2011

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112456

Indications for Use

510(k) Number: _____

Device Name: Universal Balloon Open Access Port

Indications for Use:

The ADAPt™ Universal Balloon Open Access Port is indicated for use in thoracic, abdominal, and gynecologic minimally invasive surgical procedures to provide a pathway for the introduction of endoscopic surgical devices.

Prescription Use XX AND/OR **Over-the-counter use** __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112456